UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,905	02/23/2004	Charles Ebert	2003-001	6139

28122 7590 03/31/2008

Hedman and Costigan PC
1185 Avenue of the Americas
Ste 2003
New York, NY 10036

EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
03/31/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/784,905	EBERT, CHARLES	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *11-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 25-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments over the 35 USC 103 rejection have been fully considered and are not found persuasive. In particular, Applicants argue that the Riegelman reference only exemplifies griseofulvin. Applicants also argue that van der Vies is only limited to testosterone esters having 9-16 carbon acids and does not disclose testosterone serum levels of 15ng/dl to 1200ng/dl. Applicants assert that the serum level is not merely inherent in the composition but acts as a separate element that must be fulfilled in order to read on the present claims and not every combination of PEG, MW and testosterone will produce the recited serum levels.

In response to the above arguments, it is noted that Riegelman teaches compositions comprised of griseofulvin in some of the examples in the invention; however, Riegelman teaches that the invention is drawn to increasing the absorbability of drugs including testosterone (Col. 2, lines 13-19). Further, Example VIII exemplifies a composition with 17-methyltestosterone. Accordingly, Riegelman is not only drawn to compositions comprised of griseofulvin. In regards to Applicants arguments regarding the teaching of van der Vies being limited to testosterone esters having 9-16 carbon acids, it is pointed out that Applicants assert in their specification on page 6, lines 20-22, that the term "testosterone" is intended to include its esters. Therefore, the broad term of testosterone in the claims includes the esters as taught by van der Vies. Regarding the arguments about serum levels being a separate element to be fulfilled, it is noted that the prior art teaches dose ranges of testosterone that fall within the claimed dose ranges. Because the same dose ranges are taught, it would be obvious that the serum

levels of testosterone would fall within the 15 ng/dl to about 1200 ng/dl. Absent a showing of unexpected results, in particular that the composition of the prior art does not achieve the desired serum levels in comparison to the present invention in which Applicants assert that the combination of PEG, MW and testosterone is required to provide the desired serum levels, the Examiner maintains that the rejections are proper.

Objection to the Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the specification as filed teach that the solid polyethylene glycol carriers have a molecular weight range of from about 100 to 20,000 and 1,000 to 10,000. The original claims as filed teach a range of about 400 to about 15,000 (claim 4) and about 1,000 to about 10,000 (claim 5). These weight ranges are not taught directly within the specification and it is suggested to the Applicant to include these limitations into the specification.

Claim Rejections – 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26, 27, 28 and 36 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the specification teaches that the molecular weight range of the solid polyethylene glycol carrier ranges from 100 to 20,000 and 1,000 to 10,000 specifically (page 9, lines 32-34 – page 10, lines 1-2). There is no specific teachings of weight ranges from about 100 to about 1,600 (claims 26 and 36), from about 1600 to about 5000 (claims 27and 36), from about 5000 to about 20,000 (claims 28 and 36). Accordingly, newly added claims 26-28 and 36 are considered to contain new matter.

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 and 25-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riegelman et al. (US Patent 4,151,273) in view of van der Vies (US Patent 4,098,802).

Riegelman et al. teach oral dosage formulations to increase the absorption of drugs. This includes the administration of formulations comprised of testosterone and a solid polyethylene glycol (PEG) carrier (Col. 2, lines 1-9, 13-14 and 19). It is taught that PEG has a molecular weight of 1,000 to 20,000 which closely overlaps with the range listed in claims 1, 4, 5 and 10.

Riegelman et al. does not teach the percent weight of the solid polyethylene glycol carrier or a specific dose of testosterone.

Van der Vies teaches oral dosage forms of testosterone esters with doses that fall within the range of the instant claims (see Examples 1-3 and 5 in which testosterone esters make up 10, 25 and 30 mg of the capsule). Because van der Vies teaches the same dose ranges, it would be obvious that the serum level of testosterone would fall within 15 ng/dl to about 1200 ng/dl.

Furthermore, it is obvious to vary and/or optimize the amount of the solid polyethylene glycol provided in the composition, according to the guidance provided by Riegelman et al., to provide a composition having the desired properties such as the desired percentage to effectively increase the absorbability of insoluble drugs. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Accordingly, it would be obvious to a person of ordinary skill in the art at the time of the invention to combine the teachings of Riegelman et al., which teach oral dosage formulations comprised of testosterone and a solid PEG carrier to increase the absorption of drugs, with the teachings of van der Vies which teaches oral dosage forms of testosterone esters that fall within the claimed ranges. One would be motivated to use the dosage forms taught by van der Vies in the invention of Riegelman et al. because van der Vies teaches that the dose ranges taught are therapeutically effective and have androgenic activity.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617